

SEP 30 2011

K110474

**510(k) Summary**

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Dr. Jens-Peter Seher  
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This summary was prepared on February 11, 2011.

2. The names of the devices are:

For the modified devices:

Trade Name: Philips MP40, MP50, MP60, MP70, MP80, MP90, and  
MX800 IntelliVue Patient Monitor  
Common Name: Multiparameter Patient Monitor

and

Trade Name: Philips IntelliBridge EC10 and EC5 ID Module  
Common Name: Interface Module

and

For the new device:

Trade name: Philips IntelliVue TcG10 Measurement Module  
Common name: tcpCO2/tcpO2 Measurement Module

Classification names are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	\$870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	\$870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	\$870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
Anesthesiology Devices	\$868.2480, II	LKD	Monitor, Carbon Dioxide, Cutaneous
	\$868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
	\$868.2500, II	LPP	Monitor, Oxygen, Cutaneous, for Use other than for Infant not under Gas Anesthesia

3. The modified Philips MP40, MP50, MP60, MP70, MP80, MP90, and MX800 IntelliVue Patient Monitors are substantially equivalent to the previously cleared Philips IntelliVue Patient Monitors marketed pursuant to K013199, K032858, K040304, K041235, K050762, K053522, K062392, K71426, K081793, K082633, K083517, K091927, K100939, K101449 and K102562.

The modified Philips IntelliBridge EC10 and EC5 ID modules are substantially equivalent to the previously cleared Philips IntelliBridge EC10 and EC5 ID modules marketed pursuant to K082483.

The new Philips IntelliVue TcG10 Measurement Module is substantially equivalent to the previously cleared TCM CombIM Monitoring System marketed pursuant to K093154 and in particular to the TCM CombIM Measurement Module which is the measurement unit of the TCM CombIM Monitoring System.

4. Description of the devices

The modified Philips MP40, MP50, MP60, MP70, MP80, MP90, and MX800 IntelliVue Patient Monitors are a flexible and modular monitoring solution optimized for the surgical, cardiac, general medical and neonatal care environments. The monitors can be connected to the Philips Multi-Measurement Module (MMS) family with its extensions and to the IntelliVue family plug-in measurement modules. The monitors can also be connected to the IntelliVue anesthetic gas modules and to the new IntelliVue TcG10 Measurement Module.

The modified Philips IntelliBridge EC10 and EC5 ID modules build an external medical device solution to collect data from external devices at the bedside providing the data to patient monitors, and patient monitoring networks. The modified EC10 and EC5 ID modules support the interface of the IntelliVue patient monitors with the new IntelliVue TcG10 Measurement Module.

The new IntelliVue TcG10 Measurement Module is a device for the continuous and noninvasive measurement of the transcutaneous partial pressures of blood gas carbon dioxide (pCO<sub>2</sub>) and oxygen (pO<sub>2</sub>) of patients from all pediatric subgroups and of adult patients not under gas anesthesia in hospital environment. The transcutaneous measurement of pCO<sub>2</sub> and pO<sub>2</sub> makes use of the fact that carbon dioxide and oxygen gases are able to diffuse through body tissue and skin and can be detected by a sensor placed at the skin surface. By warming up this sensor, a local hyperemia is induced, which increases the supply of arterial blood to the dermal capillary bed below the sensor. The transcutaneous blood gas values (tcpCO<sub>2</sub> and tcpO<sub>2</sub>) have to be interpreted primarily as the blood gas partial pressures prevailing at the level of the arterialized skin tissue. In general, this value correlates well with the corresponding arterial blood gas partial pressure.

#### 5. Indications for Use

IntelliVue MP40, MP50, MP60, MP70, MP80, MP90 and MX800 and IntelliBridge EC10 and EC5 IC Module:

Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

IntelliVue TcG10 Measurement Module:

Indicated for use by health care professionals whenever there is a need to support the continuous and noninvasive monitoring of transcutaneous partial pressures of blood gas carbon dioxide and oxygen of patients not under gas anesthesia.

#### 6. Technological characteristics

The modified and new devices have the same substantial technological characteristics, such as fundamental design, user interface, materials, energy source, and measurement technology, as the legally marketed predicate devices.

The modification of the Philips MP40, MP50, MP60, MP70, MP80, MP90, and MX800 IntelliVue Patient Monitors is solely limited to software changes which are necessary to interface the patient monitors to the new IntelliVue TcG10 Measurement Module via the IntelliBridge EC10 and EC5 ID Module.

The modifications of the IntelliBridge EC10 and EC5 ID Module are solely limited to software changes.

The software change for the EC10 is necessary due to the communication between the new IntelliVue TcG10 Measurement Module and the patient monitors.

The modification for the EC5 ID is necessary to add specific device identifiers for the new IntelliVue TcG10 Measurement Module.

The fundamental communication and identification procedures are not changed.

The new IntelliVue TcG10 Measurement Module uses the identical functional measurement and calibration module as the predicate device. The interface software to external devices has been modified to the general RS232 protocol and an internal power supply has been added. With this software modification and this internal power supply the IntelliVue TcG10 Measurement Module is able to operate independent of the predicate host system but now interfaced to the IntelliVue monitor family. The new IntelliVue TcG10 Measurement Module uses the identical Radiometer to Sensor 84 and the identical medical accessories, which come into contact with the patient skin, as the predicate device.

7. Brief discussion of non-clinical performance tests

The determination of substantial equivalence of the performance of the cutaneous carbon dioxide (pcCO<sub>2</sub>) and oxygen (pcO<sub>2</sub>) measurement of the new IntelliVue TcG10 Measurement Module interfaced to the modified IntelliVue patient monitors via the modified IntelliBridge EC10 and EC5 ID Modules was based on bench performance testing in accordance to the special controls guidance document "Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (pcCO<sub>2</sub>) and Oxygen (pcO<sub>2</sub>) Monitors; Guidance for Industry and FDA", document issued on December 13, 2002.

The bench performance testing has demonstrated that the system consisting of modified MP40, MP50, MP60, MP70, MP80, MP90, and MX800 IntelliVue Patient Monitors, modified IntelliBridge EC10 and EC5 ID Module and new IntelliVue TcG10 Measurement Module has performed within specifications, which have been substantial equivalent to those of the predicate device.

8. Brief discussion of clinical performance tests

Clinical data are not required in accordance to the special controls guidance document "Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO<sub>2</sub>) and Oxygen (PcO<sub>2</sub>) Monitors; Guidance for Industry and FDA", document issued on December 13, 2002, to IEC 60601-2-23:1999, and to IEC 60601-3-1:1996.

A clinical evaluation was conducted including literature review and clinical acceptance studies with experienced nursing and physician staff.

9. Conclusion nonclinical performance - clinical evaluation tests

The demonstration that the system consisting of the modified Philips MP40, MP50, MP60, MP70, MP80, MP90, and MX800 IntelliVue Patient Monitors, the modified IntelliBridge EC10 and EC5 ID Module, and the new IntelliVue TcG10 Measurement Module is as safe, as effective, and performs as the predicate devices has been demonstrated by non-clinical performance and clinical evaluation tests

10. Summary and Conclusion

Verification and validation testing activities were conducted to establish the safety, performance, functionality, and reliability characteristics of the modified and new devices with respect to the predicate devices.

V&V testing were executed including electromagnetic compatibility testing, safety and performance testing, environmental testing, regression testing and testing from the hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices.

The results demonstrate that the modified Philips MP40, MP50, MP60, MP70, MP80, MP90, and MX800 IntelliVue Patient Monitors, the modified IntelliBridge EC10 and EC5 ID Module, and the new IntelliVue TcG10 Measurement Module are as safe and as effective and perform as the predicate devices.

The modified and the new devices are substantially equivalent in intended use and fundamental technological characteristics compared to the appropriate predicate devices. The modified and new devices introduce no new questions concerning the safety or efficacy and are, therefore, substantially equivalent to the predicate devices.



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SEP 30 2011

Re: K110474

Trade/Device Name: Philips MP40, MP50, MP60, MP70, MP80, MP90, and MX800  
IntelliVue Patient Monitors, Philips IntelliBridge EC10 and EC5 ID Module, Philips  
IntelliVue TcG10 Measurement Module

Regulation Number: 21 CFR 868.2480

Regulation Name: Cutaneous Carbon Dioxide (PcCO<sub>2</sub>) Monitor

Regulatory Class: II

Product Code: LKD, KKK, LPP

Dated: September 23, 2011

Received: September 28, 2011

Dear Dr. Peter Seher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

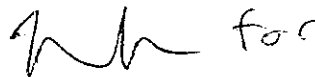
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "for" followed by a stylized signature.

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K110474

### Device Names:

- Philips MP40, MP50, MP60, MP70, MP80, MP90, and MX800 IntelliVue Patient Monitors
- Philips IntelliBridge EC10 and EC5 ID Module
- Philips IntelliVue TcG10 Measurement Module

### Indications for Use:

**IntelliVue MP40, MP50, MP60, MP70, MP80, MP90 and MX800 and IntelliBridge EC10 and EC5 IC Module:**

Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

### IntelliVue TcG10 Measurement Module:

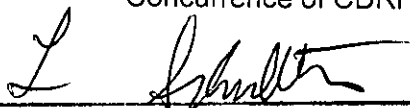
Indicated for use by health care professionals whenever there is a need to support the continuous and noninvasive monitoring of transcutaneous partial pressures of blood gas carbon dioxide and oxygen of patients not under gas anesthesia.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use         
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K 110474